OIPE
MAR 2 9 2002
PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Ross *et al.*
Serial No.: 10/007,047 Group No.:
Filed: 12/06/01 Examiner:
Entitled: **HIP1 CANCER MARKERS**

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Dated: March 21, 2002 By: Susan M. McClintock
Susan M. McClintock

Dear Sir or Madam:

Prior to the examination of this Application, Applicants respectfully request that the following amendments be entered.

Instructions to amend the specification, and replacement or added paragraphs in clean form pursuant to 37 C.F.R. §1.121(b), and a clean version of the rewritten, added, and/or cancelled claims with instructions for entry pursuant to 37 C.F.R. §1.121 (c)(1)(i) is included beginning on page 1 of this communication. A marked-up version of the specification's replacement paragraphs pursuant to 37 C.F.R. §1.121(b), as well as rewritten, added, and/or cancelled claims pursuant to 37 C.F.R. §1.121 (c)(1)(ii) is attached as Appendix I. A clean version of the entire set of pending claims pursuant to 37 C.F.R. §1.121 (c)(3) as they would appear following entry of this amendment is attached as Appendix II.

IN THE SPECIFICATION:

Please replace the paragraph beginning on page 1, line 2 with the following substitute paragraph:

This application claims priority to Provisional Patent Application Serial Number 60/335,276, filed November 15, 2001. This invention was made with government support

under Grant Nos. KO8 CA76025-05 and RO1 CA82363-02, awarded by the National Institutes of Health. The Government has certain rights in the invention.

Please replace the paragraph beginning on page 3, line 3 with the following substitute paragraph:

Accordingly, in some embodiments, the present invention provides an antibody that specifically binds to HIP1 but does not specifically bind to the normal epithelium of prostate or colon. In some embodiments, the antibody binds to the cancerous epithelium of colon or prostate but does not bind to the normal epithelium of prostate or colon. In some embodiments, the antibody is a monoclonal antibody. In some embodiments, the monoclonal antibody has substantially the same properties as antibodies secreted by a hybridoma selected from the group consisting of those deposited as ATCC numbers PTA-3901, PTA-3902 and PTA-4071. In some embodiments, the monoclonal antibody is secreted by a hybridoma with ATCC deposit number PTA-3901. In other embodiments, the monoclonal antibody is secreted by a hybridoma with ATCC deposit number PTA-3902. In still further embodiments, the monoclonal antibody specifically binds to HIP1 protein with low background binding. In yet other embodiments, the monoclonal antibody binds to human and mouse HIP1.

Please replace the paragraph beginning on page 3, line 16 with the following substitute paragraph:

The present invention also provides a method for detecting cancer, comprising providing a sample from a subject suspected of having cancer; and detecting the presence or absence of HIP1 in the sample. In some embodiments, the presence of HIP1 in said sample is indicative of cancer in the subject. In some embodiments, the cancer is selected from the group consisting of prostate cancer and colon cancer. In some embodiments, the sample is a tumor sample. In other embodiments, the sample is a tissue sample. In some embodiments, the tissue sample is selected from the group consisting of prostate tissue and colon tissue. In other embodiments, the sample is selected from the group consisting of serum, plasma, blood, and urine. In some embodiments, detecting HIP1 comprises detecting the presence of HIP1 mRNA. In some such embodiments, detecting the presence of HIP1 mRNA comprises exposing the HIP1 mRNA to a nucleic acid probe complementary to at least a portion of the

HIP1 mRNA. In some embodiments, detecting the presence of HIP1 mRNA comprises a detection assay selected from the group consisting of a Northern blot, in situ hybridization, reverse-transcriptase polymerase chain reaction, and microarray analysis. In other embodiments, detecting the presence of HIP1 comprises detecting the presence of a HIP1 polypeptide. In some embodiments, detecting the presence of a HIP1 polypeptide comprises exposing the HIP1 polypeptide to an antibody that specifically binds to HIP1 but does not specifically bind to the normal epithelium of prostate or colon and detecting the binding of the antibody to said HIP1 polypeptide. In some embodiments, the antibody is a monoclonal antibody. In some embodiments, the monoclonal antibody has substantially the same properties as antibodies secreted by a hybridoma selected from the group consisting of those deposited as ATCC numbers PTA-3901, PTA-3902 and PTA-4071. In some embodiments, the method further comprises the step of providing a prognosis to the subject.

Please replace the paragraph beginning on page 4, line 9 with the following substitute paragraph:

The present invention additionally provides a method for characterizing tissue in a subject, comprising providing a tissue sample from a subject, wherein the tissue is selected from the group consisting of colon and prostate tissue; and detecting the presence or absence of HIP1 in the sample, thereby characterizing the tissue sample. In some embodiments, the tissue is tumor tissue. In other embodiments, the tissue is biopsy tissue. In some embodiments, detecting HIP1 comprises detecting the presence of HIP1 mRNA. In some embodiments, detecting the presence of HIP1 mRNA comprises exposing the HIP1 mRNA to a nucleic acid probe complementary to at least a portion of the HIP1 mRNA. In some embodiments, detecting the presence of HIP1 mRNA comprises a detection assay selected from the group consisting of a Northern blot, in situ hybridization, reverse-transcriptase polymerase chain reaction, and microarray analysis. In other embodiments, detecting the presence of HIP1 comprises detecting the presence of a HIP1 polypeptide. In some embodiments, detecting the presence of a HIP1 polypeptide comprises exposing the HIP1 polypeptide to an antibody that specifically binds to HIP1 but does not specifically bind to the normal epithelium of prostate or colon and detecting the binding of the antibody to the HIP1 polypeptide. In some embodiments, the antibody is a monoclonal antibody. In some

embodiments, the monoclonal antibody has substantially the same properties as antibodies secreted by a hybridoma selected from the group consisting of those deposited as ATCC numbers PTA-3901, PTA-3902 and PTA-4071. In some embodiments, the tissue sample is a post-surgical prostate tumor tissue sample and the method further comprises the step of identifying a risk of prostate specific antigen failure based on detecting the presence or absence of HIP1. In other embodiments, the tissue sample is prostate tumor tissue and characterizing comprises identifying a stage of prostate cancer in the prostate tumor tissue. In some embodiments, the stage is selected from the group consisting of high-grade prostatic intraepithelial neoplasia, benign prostatic hyperplasia, prostate carcinoma, and metastatic prostate carcinoma. In other embodiments, the tissue sample is prostate tumor tissue and the method further comprises the step of identifying the risk of the tumor metastasizing based on detecting the presence of HIP1. In still further embodiments, the tissue sample is post-surgical prostate tumor tissue and the method further comprises the step of identifying the risk of the tumor recurring based on detecting the presence of HIP1.

Please replace the paragraph beginning on page 5, line 9 with the following substitute paragraph:

The present invention additionally provides a kit for characterizing cancer in a subject, comprising a reagent that specifically detects the presence of absence of expression of HIP1; and instructions for using the kit for characterizing cancer in the subject. In some embodiments, the reagent comprises an antibody that specifically binds to HIP1 but does not specifically bind to the normal epithelium of prostate or colon. In some embodiments, the antibody is a monoclonal antibody. In some embodiments, the monoclonal antibody has substantially the same properties as antibodies secreted by a hybridoma selected from the group consisting of those deposited as ATCC numbers PTA-3901, PTA-3902 and PTA-4071. In other embodiments, the reagent comprises a nucleic acid probe that specifically binds to a HIP1 mRNA. In some embodiments, the instructions comprise instructions required by the United States Food and Drug Administration for use in in vitro diagnostic products.

Please replace the paragraph beginning on page 11, line 14 with the following substitute paragraph:

As used herein, the term "a monoclonal antibody having substantially the same properties as antibodies secreted by a hybridoma selected from the group consisting of those deposited as ATCC numbers PTA-3901, PTA-3902 and PTA-4071" refers to a monoclonal antibody having substantially the same properties as those disclosed in Example 1 (ATCC numbers PTA-3901, PTA-3902 and PTA-4071), including but not limited to, specific binding to human and mouse HIP1 protein and "specifically binds to HIP1 with low background binding."

Please replace the paragraph beginning on page 61, line 24 with the following substitute paragraph:

The antibodies to HIP1 were generated by isolating a human HIP1 cDNA and creating a bacterial expression vector containing the sequences encoding the carboxyl half of the HIP1 protein. The expressed and purified recombinant protein was use to immunize mice and create monoclonal antibodies by standard methods. The specificity of the antibodies to HIP1 was confirmed by comparing Western blot analyses of murine embryonic fibroblast extracts derived from embryos with HIP1 deleted and their wild type litter mates (data not shown). Three monoclonal antibodies were found to be useful for Western blot analysis of HIP1, as well as for IHC of human tissue. These antibodies were designated HIP1-4B10, HIP1-1A1 and HIP1-1B11. Antibodies 4B10 and 1A1 recognize only human HIP1. Antibody 1B11 recognizes both human and mouse HIP1. The hybridomas producing antibodies HIP1-4B10, 1A1, HIP1-1B11 and HIP1-1A1 were deposited with ATCC under numbers PTA-3901 (HIP1-1B11), PTA-3902 (HIP1-4B10) and PTA-4071 (HIP1-1A1).

IN THE CLAIMS:

Please substitute the following claims for the previously pending Claims:

4. The monoclonal antibody of Claim 3, wherein said antibody has substantially the same properties as antibodies secreted by a hybridoma selected from the group consisting of those deposited as ATCC numbers PTA-3901, PTA-3902 and PTA-4071.

5. The monoclonal antibody of Claim 4, wherein said antibody is secreted by a hybridoma with ATCC deposit number PTA-3901.

6. The monoclonal antibody of Claim 4, wherein said antibody is secreted by a hybridoma with ATCC deposit number PTA-3902.

22. The method of Claim 21, wherein said monoclonal antibody has substantially the same properties as monoclonal antibodies secreted by a hybridoma selected from the group consisting of those deposited as ATCC numbers PTA-3901, PTA-3902 and PTA-4071.

33. The method of Claim 32, wherein said monoclonal antibody has substantially the same properties as monoclonal antibodies secreted by a hybridoma selected from the group consisting of those deposited as ATCC numbers PTA-3901, PTA-3902 and PTA-4071.

42. The kit of Claim 41, wherein said monoclonal antibody has substantially the same properties as monoclonal antibodies secreted by a hybridoma selected from the group consisting of those deposited as ATCC numbers PTA-3901, PTA-3902 and PTA-4071.

CONCLUSION

For the reasons set forth above, it is respectfully submitted that the above amendments be made prior to examination of the case. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

Dated: March 21, 2002

Tanya A. Arenson
Registration No. 47,391

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105
608.218.6900

Appendix I

Version with Markings to Show Changes Made

In the Specification:

Please amend the paragraph beginning on page 1, line 2 as follows:

Figures 10A, 10B, and 10C show an amino acid sequence alignment of human (SEQ ID NO:19), mouse (SEQ ID NO:20), and Xenopus (SEQ ID NO:21) FAST-1. This application claims priority to Provisional Patent Application Serial Number [not yet assigned] 60/335,276, filed November 15, 2001[with Express Mail Label EL837033508US]. This invention was made with government support under Grant Nos. KO8 CA76025-05 and RO1 CA82363-02, awarded by the National Institutes of Health. The Government has certain rights in the invention.

Please amend the paragraph beginning on page 3, line 3 as follows:

Accordingly, in some embodiments, the present invention provides an antibody that specifically binds to HIP1 but does not specifically bind to the normal epithelium of prostate or colon. In some embodiments, the antibody binds to the cancerous epithelium of colon or prostate but does not bind to the normal epithelium of prostate or colon. In some embodiments, the antibody is a monoclonal antibody. In some embodiments, the monoclonal antibody has substantially the same properties as antibodies secreted by a hybridoma selected from the group consisting of those deposited as ATCC numbers [pending] PTA-3901, PTA-3902 and PTA-4071. In some embodiments, the monoclonal antibody is secreted by a hybridoma with ATCC deposit number [pending] PTA-3901. In other embodiments, the monoclonal antibody is secreted by a hybridoma with ATCC deposit number [pending] PTA-3902. In still further embodiments, the monoclonal antibody specifically binds to HIP1 protein with low background binding. In yet other embodiments, the monoclonal antibody binds to human and mouse HIP1.

Please amend the paragraph beginning on page 3, line 16 as follows:

The present invention also provides a method for detecting cancer, comprising providing a sample from a subject suspected of having cancer; and detecting the presence or

absence of HIP1 in the sample. In some embodiments, the presence of HIP1 in said sample is indicative of cancer in the subject. In some embodiments, the cancer is selected from the group consisting of prostate cancer and colon cancer. In some embodiments, the sample is a tumor sample. In other embodiments, the sample is a tissue sample. In some embodiments, the tissue sample is selected from the group consisting of prostate tissue and colon tissue. In other embodiments, the sample is selected from the group consisting of serum, plasma, blood, and urine. In some embodiments, detecting HIP1 comprises detecting the presence of HIP1 mRNA. In some such embodiments, detecting the presence of HIP1 mRNA comprises exposing the HIP1 mRNA to a nucleic acid probe complementary to at least a portion of the HIP1 mRNA. In some embodiments, detecting the presence of HIP1 mRNA comprises a detection assay selected from the group consisting of a Northern blot, in situ hybridization, reverse-transcriptase polymerase chain reaction, and microarray analysis. In other embodiments, detecting the presence of HIP1 comprises detecting the presence of a HIP1 polypeptide. In some embodiments, detecting the presence of a HIP1 polypeptide comprises exposing the HIP1 polypeptide to an antibody that specifically binds to HIP1 but does not specifically bind to the normal epithelium of prostate or colon and detecting the binding of the antibody to said HIP1 polypeptide. In some embodiments, the antibody is a monoclonal antibody. In some embodiments, the monoclonal antibody has substantially the same properties as antibodies secreted by a hybridoma selected from the group consisting of those deposited as ATCC numbers [pending] PTA-3901, PTA-3902 and PTA-4071. In some embodiments, the method further comprises the step of providing a prognosis to the subject.

Please amend the paragraph beginning on page 4, line 9 as follows:

The present invention additionally provides a method for characterizing tissue in a subject, comprising providing a tissue sample from a subject, wherein the tissue is selected from the group consisting of colon and prostate tissue; and detecting the presence or absence of HIP1 in the sample, thereby characterizing the tissue sample. In some embodiments, the tissue is tumor tissue. In other embodiments, the tissue is biopsy tissue. In some embodiments, detecting HIP1 comprises detecting the presence of HIP1 mRNA. In some embodiments, detecting the presence of HIP1 mRNA comprises exposing the HIP1 mRNA to a nucleic acid probe complementary to at least a portion of the HIP1 mRNA. In some

embodiments, detecting the presence of HIP1 mRNA comprises a detection assay selected from the group consisting of a Northern blot, in situ hybridization, reverse-transcriptase polymerase chain reaction, and microarray analysis. In other embodiments, detecting the presence of HIP1 comprises detecting the presence of a HIP1 polypeptide. In some embodiments, detecting the presence of a HIP1 polypeptide comprises exposing the HIP1 polypeptide to an antibody that specifically binds to HIP1 but does not specifically bind to the normal epithelium of prostate or colon and detecting the binding of the antibody to the HIP1 polypeptide. In some embodiments, the antibody is a monoclonal antibody. In some embodiments, the monoclonal antibody has substantially the same properties as antibodies secreted by a hybridoma selected from the group consisting of those deposited as ATCC numbers [pending] PTA-3901, PTA-3902 and PTA-4071. In some embodiments, the tissue sample is a post-surgical prostate tumor tissue sample and the method further comprises the step of identifying a risk of prostate specific antigen failure based on detecting the presence or absence of HIP1. In other embodiments, the tissue sample is prostate tumor tissue and characterizing comprises identifying a stage of prostate cancer in the prostate tumor tissue. In some embodiments, the stage is selected from the group consisting of high-grade prostatic intraepithelial neoplasia, benign prostatic hyperplasia, prostate carcinoma, and metastatic prostate carcinoma. In other embodiments, the tissue sample is prostate tumor tissue and the method further comprises the step of identifying the risk of the tumor metastasizing based on detecting the presence of HIP1. In still further embodiments, the tissue sample is post-surgical prostate tumor tissue and the method further comprises the step of identifying the risk of the tumor recurring based on detecting the presence of HIP1.

Please amend the paragraph beginning on page 5, line 9 as follows:

The present invention additionally provides a kit for characterizing cancer in a subject, comprising a reagent that specifically detects the presence of absence of expression of HIP1; and instructions for using the kit for characterizing cancer in the subject. In some embodiments, the reagent comprises an antibody that specifically binds to HIP1 but does not specifically bind to the normal epithelium of prostate or colon. In some embodiments, the antibody is a monoclonal antibody. In some embodiments, the monoclonal antibody has substantially the same properties as antibodies secreted by a hybridoma selected from the

group consisting of those deposited as ATCC numbers [pending] PTA-3901, PTA-3902 and PTA-4071. In other embodiments, the reagent comprises a nucleic acid probe that specifically binds to a HIP1 mRNA. In some embodiments, the instructions comprise instructions required by the United States Food and Drug Administration for use in in vitro diagnostic products.

Please amend the paragraph beginning on page 11, line 14 as follows:

As used herein, the term "a monoclonal antibody having substantially the same properties as antibodies secreted by a hybridoma selected from the group consisting of those deposited as ATCC numbers [pending] PTA-3901, PTA-3902 and PTA-4071" refers to a monoclonal antibody having substantially the same properties as those disclosed in Example 1 (ATCC numbers [pending] PTA-3901, PTA-3902 and PTA-4071), including but not limited to, specific binding to human and mouse HIP1 protein and "specifically binds to HIP1 with low background binding."

Please amend the paragraph beginning on page 61, line 24 as follows:

The antibodies to HIP1 were generated by isolating a human HIP1 cDNA and creating a bacterial expression vector containing the sequences encoding the carboxyl half of the HIP1 protein. The expressed and purified recombinant protein was use to immunize mice and create monoclonal antibodies by standard methods. The specificity of the antibodies to HIP1 was confirmed by comparing Western blot analyses of murine embryonic fibroblast extracts derived from embryos with HIP1 deleted and their wild type litter mates (data not shown). Three monoclonal antibodies were found to be useful for Western blot analysis of HIP1, as well as for IHC of human tissue. These antibodies were designated HIP1-4B10, HIP1-1A1 and HIP1-1B11. Antibodies 4B10 and 1A1 recognize only human HIP1. Antibody 1B11 recognizes both human and mouse HIP1. The hybridomas producing antibodies HIP1-4B10, 1A1 [and] HIP1-1B11 and HIP1-1A1 were deposited with ATCC under numbers [pending] PTA-3901 (HIP1-1B11), PTA-3902 (HIP1-4B10) and PTA-4071 (HIP1-1A1).

In the Claims:

4. (once amended) The monoclonal antibody of Claim 3, wherein said antibody has substantially the same properties as antibodies secreted by a hybridoma selected from the group consisting of those deposited as ATCC numbers [pending] PTA-3901, PTA-3902 and PTA-4071.

5. (once amended) The monoclonal antibody of Claim 4, wherein said antibody is secreted by a hybridoma with ATCC deposit number [pending] PTA-3901.

6. (once amended) The monoclonal antibody of Claim 4, wherein said antibody is secreted by a hybridoma with ATCC deposit number [pending] PTA-3902.

22. (once amended) The method of Claim 21, wherein said monoclonal antibody has substantially the same properties as monoclonal antibodies secreted by a hybridoma selected from the group consisting of those deposited as ATCC numbers [pending] PTA-3901, PTA-3902 and PTA-4071.

33. (once amended) The method of Claim 32, wherein said monoclonal antibody has substantially the same properties as monoclonal antibodies secreted by a hybridoma selected from the group consisting of those deposited as ATCC numbers [pending] PTA-3901, PTA-3902 and PTA-4071.

42. (once amended) The kit of Claim 41, wherein said monoclonal antibody has substantially the same properties as monoclonal antibodies secreted by a hybridoma selected from the group consisting of those deposited as ATCC numbers [pending] PTA-3901, PTA-3902 and PTA-4071.

Appendix II

Pending Claims

1. An antibody that specifically binds to HIP1 but does not specifically bind to the normal epithelium of prostate or colon.

2. The antibody of Claim 1, wherein said antibody binds to the cancerous epithelium of colon or prostate but does not bind to the normal epithelium of prostate or colon.

3. The antibody of Claim 1, wherein said antibody is a monoclonal antibody.

4. The monoclonal antibody of Claim 3, wherein said antibody has substantially the same properties as antibodies secreted by a hybridoma selected from the group consisting of those deposited as ATCC numbers PTA-3901, PTA-3902 and PTA-4071.

5. The monoclonal antibody of Claim 4, wherein said antibody is secreted by a hybridoma with ATCC deposit number PTA-3901.

6. The monoclonal antibody of Claim 4, wherein said antibody is secreted by a hybridoma with ATCC deposit number PTA-3902.

7. The monoclonal antibody of Claim 4, wherein said antibody specifically binds to HIP1 protein with low background binding.

8. The monoclonal antibody of Claim 4, wherein said antibody binds to human and mouse HIP1.

9. A method for detecting cancer, comprising:

a) providing a sample from a subject suspected of having cancer; and

b) detecting the presence or absence of HIP1 in said sample.

10. The method of Claim 9, wherein the presence of HIP1 in said sample is indicative of cancer in said subject.

11. The method of Claim 9, wherein said cancer is selected from the group consisting of prostate cancer and colon cancer.

12. The method of Claim 9, wherein said sample is a tumor sample.

13. The method of Claim 9, wherein said sample is a tissue sample.

14. The method of Claim 13, wherein said tissue sample is selected from the group consisting of prostate tissue and colon tissue.

15. The method of Claim 9, wherein said sample is selected from the group consisting of serum, plasma, blood, and urine.

16. The method of Claim 8, wherein said detecting HIP1 comprises detecting the presence of HIP1 mRNA.

17. The method of Claim 16, wherein said detecting the presence of HIP1 mRNA comprises exposing said HIP1 mRNA to a nucleic acid probe complementary to at least a portion of said HIP1 mRNA.

18. The method of Claim 17, wherein said detecting the presence of HIP1 mRNA comprises a detection assay selected from the group consisting of a Northern blot, in situ hybridization, reverse-transcriptase polymerase chain reaction, and microarray analysis.

19. The method of Claim 9, wherein said detecting the presence of HIP1 comprises detecting the presence of a HIP1 polypeptide.

20. The method of Claim 17, wherein said detecting the presence of a HIP1 polypeptide comprises exposing said HIP1 polypeptide to an antibody that specifically binds to HIP1 but does not specifically bind to the normal epithelium of prostate or colon and detecting the binding of said antibody to said HIP1 polypeptide.

21. The method of Claim 20, wherein said antibody is a monoclonal antibody.

22. The method of Claim 21, wherein said monoclonal antibody has substantially the same properties as monoclonal antibodies secreted by a hybridoma selected from the group consisting of those deposited as ATCC numbers PTA-3901, PTA-3902 and PTA-4071.

23. The method of Claim 9, wherein said method further comprises step c) providing a prognosis to said subject.

24. A method for characterizing tissue in a subject, comprising:

a) providing a tissue sample from a subject, wherein said tissue is selected from the group consisting of colon and prostate tissue; and

b) detecting the presence or absence of HIP1 in said sample, thereby characterizing said tissue sample.

25. The method of Claim 24, wherein said tissue is tumor tissue.

26. The method of Claim 24, wherein said tissue is biopsy tissue.

27. The method of Claim 24, wherein said detecting HIP1 comprises detecting the presence of HIP1 mRNA.

28. The method of Claim 27, wherein said detecting the presence of HIP1 mRNA comprises exposing said HIP1 mRNA to a nucleic acid probe complementary to at least a portion of said HIP1 mRNA.

29. The method of Claim 28, wherein said detecting the presence of HIP1 mRNA comprises a detection assay selected from the group consisting of a Northern blot, in situ hybridization, reverse-transcriptase polymerase chain reaction, and microarray analysis.

30. The method of Claim 24, wherein said detecting the presence of HIP1 comprises detecting the presence of a HIP1 polypeptide.

31. The method of Claim 30, wherein said detecting the presence of a HIP1 polypeptide comprises exposing said HIP1 polypeptide to an antibody that specifically binds to HIP1 but does not specifically bind to the normal epithelium of prostate or colon and detecting the binding of said antibody to said HIP1 polypeptide.

32. The method of Claim 31, wherein said antibody is a monoclonal antibody.

33. The method of Claim 32, wherein said monoclonal antibody has substantially the same properties as monoclonal antibodies secreted by a hybridoma selected from the group consisting of those deposited as ATCC numbers PTA-3901, PTA-3902 and PTA-4071.

34. The method of Claim 24, wherein said tissue sample is a post-surgical prostate tumor tissue sample and said method further comprises the step of c) identifying a risk of prostate specific antigen failure based on said detecting the presence of HIP1.

35. The method of Claim 24, wherein said tissue sample is prostate tumor tissue and said characterizing comprises identifying a stage of prostate cancer in said prostate tumor tissue.

36. The method of Claim 35, wherein said stage is selected from the group consisting of high-grade prostatic intraepithelial neoplasia, benign prostatic hyperplasia, prostate carcinoma, and metastatic prostate carcinoma.

37. The method of Claim 24, wherein said tissue sample is prostate tumor tissue and said method further comprises the step of c) identifying the risk of said tumor metastasizing based on said detecting the presence of HIP1.

38 The method of Claim 24, wherein said tissue sample is post-surgical prostate tumor tissue and said method further comprises the step of c) identifying the risk of said tumor recurring based on said detecting the presence of HIP1.

39. A kit for characterizing cancer in a subject, comprising:

a) a reagent that specifically detects the presence of absence of expression of HIP1; and

b) instructions for using said kit for characterizing cancer in said subject.

40. The kit of Claim 39, wherein said reagent comprises an antibody that specifically binds to HIP1 but does not specifically bind to the normal epithelium of prostate or colon.

41. The kit of Claim 40, wherein said antibody is a monoclonal antibody.

42. The kit of Claim 41, wherein said monoclonal antibody has substantially the same properties as monoclonal antibodies secreted by a hybridoma selected from the group consisting of those deposited as ATCC numbers PTA-3901, PTA-3902 and PTA-4071.

43. The kit of Claim 39, wherein said reagent comprises a nucleic acid probe that specifically binds to a HIP1 mRNA.

44. The kit of Claim 39, wherein said instructions comprise instructions required by the United States Food and Drug Administration for use in in vitro diagnostic products.

45. A method of screening compounds, comprising:

a) providing

i) an cell sample comprising cancerous epithelial cells; and

ii) one or more test compounds; and

b) contacting said sample with said test compound; and

c) detecting a change in HIP1 expression in said sample in the presence of said test compound relative to the absence of said test compound.

46. The method of Claim 45, wherein said contacting said sample with said test compound results in death of said cancerous epithelial cells.

47. The method of Claim 45, wherein said contacting said sample with said test compound results in impaired proliferation of said cancerous epithelial cells.

48. The method of Claim 45, wherein said epithelial cell sample is selected from the group consisting of prostate cancer cells and colon cancer cells.

49. The method of Claim 45, wherein said detecting comprises detecting HIP1 mRNA.

50. The method of Claim 45, wherein said detecting comprises detecting HIP1 polypeptide.

51. The method of Claim 45, wherein said cell is in vitro.

52. The method of Claim 45, wherein said cell is in vivo.

53. The method of Claim 45, wherein said test compound comprises an antisense compound.

54. The method of Claim 45, wherein said test compound comprises a drug.

55. The method of Claim 54, wherein said drug is an antibody.

56. The method of Claim 54, wherein said drug specifically binds to HIP1.

57. A method of screening compounds, comprising:

a) providing

i) a first cell sample comprising cells expressing wild-type HIP1;

ii) a second cell sample comprising cells, wherein said cells do not express HIP1;

iii) one or more test compounds; and

b) contacting said first and seconds samples with said test compound; and

c) detecting a decrease in viability in said first sample relative to said second sample.

58. The method of Claim 57, wherein said decrease in viability is due to programmed cell death.

59. The method of Claim 57, wherein said first and second cell samples comprise embryonic fibroblast cells.

60. The method of Claim 58, wherein first cell sample comprises embryonic fibroblast cells derived from wild-type mice.

61. The method of Claim 59, wherein said second cell sample comprises embryonic fibroblast cells derived from HIP1 knockout mice.

62. The method of Claim 57, wherein said first and second cell samples comprise first and second human cancer cell lines.

63. The method of Claim 62, wherein said second human cancer cell line is colo205 cells.

64. The method of Claim 57, wherein said test compound comprises a library of test compounds.

65. The method of Claim 57, wherein said test compound comprises a lipid analogue.

66. The method of Claim 57, wherein said test compound binds to HIP1.

67. The method of Claim 66, wherein said test compound binds to the ENTH domain of HIP1.

68. A composition comprising a mutant HIP1 nucleic acid sequence, said sequence lacking the ENTH domain.

69. The composition of Claim 68, wherein said nucleic acid sequence comprises SEQ ID NO: 3.

70. A composition comprising a polypeptide encoded by the nucleic acid sequence of Claim 68.

71. A composition comprising a mutant HIP1 polypeptide, wherein said polypeptide induces cell death when expressed in a cell.

72. The composition of Claim 71, wherein said mutant HIP1 polypeptide is lacking a ENTH domain.

73. The composition of Claim 72, wherein said HIP1 polypeptide comprises SEQ ID NO: 4.

74. A nucleic acid sequence encoding the polypeptide of Claim 71.

75. A non-human transgenic animal lacking a functional HIP1 gene.

76. The non-human transgenic animal of Claim 75, wherein said animal is a mouse.

77. The non-human transgenic animal of Claim 75, wherein said animal comprises a knock-out of the HIP1 gene.

78. The non-human transgenic animal of Claim 76, wherein said knock-out of the HIP1 gene is a conditional knock-out.

79. The non-human transgenic animal of Claim 75, wherein said animal comprises a knock-in of the HIP1 gene.

80. A composition comprising a drug, wherein said drug binds to wild type HIP1 but not a HIP1 ENTH deletion mutant, and wherein said drug inhibits HIP1 biological activity.

81. The composition of Claim 80, wherein said drug binds to the ENTH domain of HIP1.

82. The composition of Claim 81, wherein said drug is a lipid analogue.

83. The composition of Claim 82, wherein said lipid analogue is a phosphoinositide mimetic.